IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE BIOGEN '755 PATENT LITIGATION	)	Hon. Claire C. Cecchi No. 10-cv-2734-CCC-JBC (consolidated)

BIOGEN'S MOTION TO STRIKE THE REPORT OF BAYER'S EXPERT GORDON P. MOORE, AND TO PRECLUDE BAYER FROM USING A PREVIOUSLY UNDISCLOSED INVALIDITY CONTENTION AND INFORMATION ON WHICH IT IS BASED

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PRELIMINARY STATEMENT

Biogen MA Inc. ("Biogen") respectfully submits this motion, pursuant to Fed. R. Civ. P. 16 and 37, Local Patent Rules 3.3 and 3.4 and the Court's inherent authority to manage discovery, to strike the report of Dr. Gordon P. Moore, one of the experts retained by defendant Bayer HealthCare Pharmaceuticals, Inc. ("Bayer"). Biogen further seeks to preclude Bayer from using the opinions expressed in the Moore report at trial or in other proceedings in this action. The basis for the motion is that Bayer deliberately withheld the information in question for more than four years, despite Biogen's repeated requests for it in discovery, and the untimely disclosure has now resulted in irremediable prejudice to Biogen.

Dr. Moore's report addresses whether certain alleged prior art meets a limitation of claim 1 of Biogen's U.S. Patent No. 7,588,755 ("the '755 Patent"). The limitation in question defines a class of DNA molecules that can be used to create the material—a "recombinant polypeptide"—used to practice the method of the invention. The limitation requires that the DNA in question must be "capable of hybridizing" to one of four reference DNA molecules listed in the claim.

Dr. Moore has conducted tests on the basis of which he opines that DNA from a prior art patent satisfies the "capable of hybridizing" limitation. However, Bayer failed to address the "capable of hybridizing" requirement when it provided its invalidity contentions in 2011, and likewise failed to produce the supporting

documentation cited in the Moore report. This violated Local Patent Rules 3.3 and 3.4. When Biogen propounded an interrogatory to backstop the invalidity contentions requirement, Bayer again failed to disclose its contention or the underlying information. This violated Federal Rule 33.

Biogen pursued the issue in a meet-and-confer dialog, in which Bayer unequivocally stated that "Bayer is not withholding or refusing to identify documents or testimony that it currently believes are responsive to Biogen's interrogatories," and "at this time we do not believe there is anything to add and compel." Declaration of Steven M. Balcof ("Balcof Decl."), Ex. K (March 22, 2013 e-mail). Biogen relied on this representation in not moving to compel.

In July 2016—more than three years later—Bayer served the Moore report, which asserted the "capable of hybridizing" contention for the first time. The report shows that the underlying work took place from April 2011 until August 2012—well within the fact discovery period and before Bayer represented to Biogen, wrongly, that it did not have any such contentions or supporting evidence.

Bayer's surprise tactics have prejudiced Biogen and cannot be cured at this late stage, less than a year from trial. Most importantly, Bayer's decision not to disclose its position resulted in a failure to address at least two claim construction disputes regarding the meaning of the term "capable of hybridizing" itself, and also the meaning of a related term, "washing conditions." Bayer began the work

embodied in the Moore report as far back as April 2011 and thus could have disclosed its position in time for these disputes to have been briefed and argued with all the other claim construction issues, and duly decided by the Court. The prospect of having to reopen claim construction to construe at least two new terms is so prejudicial by itself to warrant granting this motion.

Likewise, if Biogen had known of Bayer's testing, Biogen could have taken depositions and other fact discovery about it before memories faded. Biogen would have explored potential shortcomings in how the tests were conducted, and would also have taken third party discovery aimed at establishing that the material tested was not in fact part of the prior art. But fact discovery closed more than three years ago and those options are simply no longer available to Biogen.

To be clear, Biogen believes that there are serious problems with Bayer's testing methodology and conclusions. Biogen served a rebuttal expert report detailing these problems, and Biogen will rely on its rebuttal report if Dr. Moore's report is not stricken, to the prejudice of Biogen. But it is now far too late for Biogen to prepare a complete response. This could have been avoided if Bayer complied with its disclosure obligations and Bayer must bear the consequences.

FACTS & PROCEDURAL HISTORY

The Relevant Claim Limitations. Claim 1 of the '755 Patent claims a method of treatment with a "recombinant polypeptide" created using a recombinant

DNA molecule comprising one of the following:

> (a) DNA sequences which are ***capable of hybridizing*** to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C. and ***washing conditions*** of 0.3 M NaCl at 68° C., and which code for a polypeptide displaying antiviral activity, and
>
> (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a). (Emphasis added.)

Hybridizing refers to the ability of two pieces of DNA to bind to one another because of the complementary nature of their respective DNA sequences—in essence like a lock and key fitting together. This claim limitation limits the DNA to those sequences that will hybridize or bind to certain defined pieces of DNA identified as HFIF1, HFIF3, HFIF6 and HFIF7. Importantly, the claim also requires certain "washing conditions." This refers to the use of a washing step in order to remove DNA that is not truly hybridized, but merely attached in some other, more transient fashion. The specification provides details of the required washing conditions. Balcof Decl., Ex. B ('755 Patent) at *e.g.* col. 24, ll. 9-12.

Bayer's Invalidity Argument. Bayer contends that the '755 Patent is invalid for numerous reasons including that it is allegedly anticipated by an earlier Biogen patent, U.S. Patent No. 5,530,901, also known as "Weissmann" or "the Weissmann patent." The '755 Patent is directed to the use of recombinant polypeptides that have the same biological activity as the natural polypeptide known as interferon beta. By

contrast, the Weissmann patent is directed to a different recombinant polypeptide known as interferon alpha. That polypeptide was isolated by a different group of Biogen scientists (led by Dr. Weissmann) and is expressly distinguished in the '755 Patent. *Id.* at col. 5 ll. 16-20.

It is black letter patent law that anticipation requires a showing that a single prior art reference expressly or inherently discloses every single limitation of the patent claim at issue. *Purdue Pharma L.P. v. Epic Pharma, LLC*, 811 F.3d 1345, 1351 (Fed. Cir. 2016); *Schering Corp. v. Geneva Pharm.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003). Thus, it was incumbent upon Bayer to show how the Weissmann patent disclosed every limitation of claim 1 of the '755 Patent. Patent Local Rule 3.3(c) obligates a patent challenger to provide, as part of its invalidity contentions, "a chart identifying where specifically in each item of alleged prior art each limitation of each asserted claim is found." And, where such a contention is based on underlying documents, Patent Local Rule 3.4(c) obligates the patent challenger to produce the documents.

Accordingly, to show anticipation, Bayer was required to submit a chart showing how each limitation of claim 1—including "capable of hybridizing" and "washing conditions"—were met in the Weissmann patent. Bayer failed to do this. On July 22, 2011, after it had begun the work addressed in the Moore report, Bayer served invalidity contentions for the Weissmann patent but, as shown below, the

relevant part of its claim chart omitted any reference whatsoever to the "capable of hybridizing" and "washing conditions" limitations:

Claim Limitation	Citations
comprising a DNA sequence selected from the group consisting of (a) DNA sequences which are capable of hybridizing to any of the DNA inserts of G-pBR322(Pst)/HFIF1, G-pBR322(Pst)/HFIF3 (DSM 1791), G-pBR322(Pst)/HFIF6 (DSM 1792), and G-pBR322(Pst)/HFIF7 (DSM 1793) under hybridizing conditions of 0.75 M NaCl at 68° C. and washing conditions of 0.3 M NaCl at 68° C. . . ., and (b) DNA sequences which are degenerate as a result of the genetic code to the DNA sequences defined in (a)	Weissmann discloses the administration to a patient in need of such treatment, a therapeutically effective amount of interferon, *id.* at col. 2, ll. 57-63, col. 3, ll. 6-16, 27- 41, col. 5, ll. 49-54, where the interferon polypeptide is produced by a non-human host transformed by a recombinant DNA molecule that encodes the interferon, which DNA molecule is operatively linked to an expression control sequence and codes for a polypeptide displaying antiviral activity. *Id.* at col. 2, ll. 57-63, col. 3, ll. 6-16, 27-41, col. 5, ll. 34-44, 49-54, cols. 30-32, ll. 61-16.

Balcof Decl., Ex. C (Exhibit B to Bayer's 7/22/11 Second Amended Invalidity Contentions) at 96. As can readily be seen, Bayer's claim chart is completely silent with respect to the "capable of hybridizing" and "washing conditions" claim limitations. Likewise, none of the passages it cites from the Weissmann patent discusses these limitations in any way.

Biogen's Efforts to Obtain Discovery. Biogen also served formal discovery requests seeking disclosure of Bayer' invalidity theories and the facts on which such theories are based. In particular, at the beginning of the discovery period Biogen

served its Interrogatory 2, asking Bayer to "state in detail all facts that support each Defendant's contention that each Asserted Claim is invalid" that were not disclosed in Bayer's invalidity contentions, and "Identify all witnesses to any facts and all documents (whether supporting or not supporting such facts) relating or referring to any of the foregoing." Balcof Decl., Ex. D. Bayer initially objected to this interrogatory as premature but in 2013, it filed a supplemental response incorporating by reference its invalidity contentions. Balcof Decl., Exs. E and F (Bayer's original and supplemental responses from 2010 and 2013). Neither the original nor supplemental responses said or identified anything about "capable of hybridizing" or "washing conditions," *see id.*, even though Bayer completed the Moore testing in 2012 before serving the supplemental responses.

Concerned that important information was being withheld, Biogen initiated a meet-and-confer process regarding Interrogatory 2 in order to ensure that it had received full disclosure of Bayer's invalidity contentions and any alleged support for those contentions. At the conclusion of the meet and confer exchange, in March 2013, Bayer stated that "Bayer is not withholding or refusing to identify documents or testimony that it currently believes are responsive to Biogen's interrogatories," and "at this time we do not believe there is anything to add and compel." Balcof Decl., Ex. K (March 22, 2013 e-mail).[1] Bayer made this statement even though it

[1] Bayer's email made one exception for the testimony of a witness who had been

had completed the Moore testing in August 2012, more than six months earlier.

As Biogen made clear at the time, it relied on this representation and did not move to compel further responses because Bayer had said there was no additional responsive information and thus—if the representation were correct—a motion would have been pointless. *Id*. It has since become clear that Bayer's representation was not correct.

The Moore Report. Fact discovery closed in 2013. Over three years later, in July 2016, Bayer served the expert report of Dr. Moore which for the first time disclosed the testing that is the subject of the present motion. The Moore report describes certain experiments involving a DNA sequence called "clone 4," which is not the DNA of interferon alpha but is allegedly a related DNA sequence. Dr. Moore purports to show that this DNA is "capable of hybridizing" to certain of the DNA sequences listed in Biogen's claim 1. *See* Balcof Decl., Ex. A (Moore Report) at ¶¶ 53, 120, 122. The work Dr. Moore describes was conducted between April 2011 and August 2012 and is documented in two laboratory notebooks, "Notebooks 142 and 151." *See id.* at ¶¶ 54, 60; Balcof Decl., Ex. H (Marin Laboratory Notebook 142), Ex. I (Marin Laboratory Notebook 151).

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deposed too recently for his information to have been added to the interrogatory response, but that testimony concerned other theories and was irrelevant to Bayer's arguments regarding invalidity over the '901 patent.

Although Dr. Moore does not mention the Weissmann patent, and instead relies on an article by Mantei *et al.*, Bayer relies on Dr. Moore's work to supply what was missing from its invalidity contentions, *i.e.* the assertion that the polypeptide of the Weissmann patent meets the "capable of hybridizing" claim limitation. *See* Balcof Decl., Ex. M (Ravetch Report) at ¶¶ 20, 818-827.

ARGUMENT

The Third Circuit has identified a series of factors to be weighed in deciding whether to preclude evidence. *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904-905 (3d Cir. 1977). Judge Wolfson's decision in *Reckitt Benckiser Inc.* v. *Tris Pharma, Inc.*, 2011 WL 6722707 (D.N.J. Dec. 20, 2011), aptly sets forth how the *Pennypack* factors should be applied in deciding a motion to strike an expert report for failure to make discovery:

> It is well established that a court has discretion to exclude evidence for a party's failure to adhere to the schedule set by the court. *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791 (3d Cir. 1994). The Third Circuit has established four factors that a court should balance before precluding evidence. *Meyers*, 559 F.2d 894. Along with the importance of the excluded testimony, the *Pennypack* factors include: (1) the prejudice or surprise in fact of the party against whom the excluded witnesses would have testified; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of the rule against calling unlisted witnesses would disrupt the orderly and efficient trial of the case or other cases in the court; and (4) bad faith or willfulness in failing to comply with the court's order. *Id.* at 904–05.

Reckitt Benckiser, at *6. Each *Pennypack* factor supports striking the Moore report and precluding Bayer from relying on the information contained in it. This result

would give effect to the general rule that "[a] party that fails to include a theory in its invalidity contentions cannot advance that theory at trial." *Changzhou Kaidi Elec. Co.* v. *Okin Am., Inc.*, 112 F. Supp. 3d 330, 332-39 (D. Md. 2015).

I. Bayer's Surprise Tactics Prejudiced Biogen By Frustrating Claim Construction And Denying Biogen A Fair Opportunity To Take Discovery In Response

It is clear from the Moore report that Bayer and Biogen have very significant differences with respect to the proper construction of the claim terms "capable of hybridizing" and "washing conditions." Had Bayer disclosed its contentions years ago as it should have done, these differences could and would have been resolved as part of the claim construction proceedings. By failing to make the required disclosures Bayer prevented that from happening and Biogen has to proceed without the benefit of the Court's guidance on the meaning of these terms.

In May 2011, the parties submitted an agreed construction of "capable of hybridizing." Joint Claim Construction Statement [D.I. 100] at 3. However, it is now clear that this agreed construction fails to resolve a fundamental dispute that goes to the heart of whether Dr. Moore's tests do or do not comply with the requirements of the '755 Patent. In particular, the agreed construction states that hybridization must produce a result that is "above background." *Id.* "Background" refers to false positive information that results from mechanisms other than hybridization, and needs to be distinguished to confirm that hybridization in fact

occurred. One mechanism for a false positive is so-called "non-specific binding" not caused by hybridization between the specific "lock and key" DNA sequences. "The point of accounting for background is to ensure that the signal represents specific binding of the probe to the target [which would support hybridization] rather than non-specific binding [which would not]." Balcof Decl., Ex. L (Couceyro Rebuttal Report) at 19.

Dr. Couceyro has submitted a rebuttal expert report detailing why, in his opinion, Dr. Moore's experiments failed to show results "above background." *See id.* at 18-19. While there are undoubtedly factual disputes between the two experts, the fundamental problem is the lack of a clear definition of how the tests should be run. This underlying dispute is one of claim construction: in essence, the two experts disagree about the meaning of the agreed construction and thus the construction is not agreed at all. If Bayer is allowed to proceed with its newly-disclosed theory, the Court will have to engage in a "construction of the construction" in order to resolve the question of how one tells whether a particular test result does or does not indicate that hybridization has taken place, as opposed to a false positive attributable to a background signal.

And if Bayer had made a timely disclosure of its contentions, that is exactly what would have happened. The parties submitted the agreed construction of "capable of hybridizing" to the Court in May 2011, ***after*** Bayer began its

experiments in April 2011. *See* Joint Claim Construction Statement [D.I. 100]. Had Bayer been forthcoming, the claim construction disputes could have been briefed then and decided by the Court, and Biogen would now be able to prepare expert reports based on whatever constructions the Court adopted.

There is also now a dispute regarding the "washing conditions" requirement of claim 1. In Dr. Couceyro's view, Bayer's experiment failed to include adequate washing to eliminate non-specific binding and failed to follow the teachings of the '755 Patent as to how the wash step should be carried out. Balcof Decl., Ex. L (Couceyro Rebuttal Report) at 16-18. This of course leads directly to the question of what are the requirements of the "washing conditions" recited in claim 1—in other words, a claim construction dispute. Because Bayer failed to disclose its test results or the underlying invalidity theory, the term "washing conditions" was never identified as one in need of construction and thus its meaning was never briefed or decided. If Bayer is permitted to rely on the Moore report, the Court will have to engage in further claim construction to define the proper legal scope of this term as a predicate to deciding whether Dr. Moore's tests were or were not conducted in accordance with the requirements of claim 1.

The Moore report also asserts that if Biogen disagrees with its conclusions then claim 1 is indefinite. *See* Balcof Decl., Ex. A (Moore Report) at ¶¶ 124-125. This is yet another previously undisclosed invalidity contention that should have

been provided in both Bayer's disclosure under Local Patent Rule 3.3 and its answer to Interrogatory No. 2. Further, it also raises new and untimely claim construction issues: "As part of construing claims, the Court can assess whether a claim term is indefinite, and reach "'a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims.'" *Horizon Pharma Ireland Ltd.* v. *Actavis Labs., UT, Inc.*, 2016 WL 4408990, at *2 (D.N.J. Aug. 17, 2016) (quoting *In re Aoyama*, 656 F.3d 1293, 1299 (Fed. Cir. 2011)).

The very serious problems with Bayer's experimental methodology also beg for fact discovery into what specifically the people performing the testing did and why they did it. If Bayer had disclosed these theories in 2011, Biogen could have taken depositions of the individuals at the contract lab that did the tests in order to learn exactly what procedures were followed. Similarly, Biogen could have pursued third-party fact discovery to show that the material Dr. Moore tested was not publicly available at the time required to qualify it as prior art. But now fact discovery is long since over and these options are not available.

Bayer asserts that Biogen can perform testing of its own, but this ignores the even more fundamental prejudice to Biogen's claim construction and fact discovery, and it ignores that Biogen cannot realistically perform the testing in real time as it prepares for trial. The plaintiffs in *Reckitt Benckiser* similarly asserted that "there was sufficient time for [the injured party] to address the supplemental data";

"nothing precluded [the injured party] from conducting its own tests prior to trial"; and the injured party's "inability to find a qualified expert was not [the wrongdoer's] fault." 2011 WL 6722707 at *6. The Court found these claims "disingenuous in light of [the wrongdoer's] certain knowledge that the data resulting from the third party testing would not be completed until [a date] well after expert reports were due and just weeks short of trial." *Id.* at *8.

Moreover, regardless of what Bayer now says, its actions have frustrated Biogen from conducting its own testing in response. First, the work on Bayer's experiment took more than sixteen months—from April 2011 to August 2012. But Bayer did not produce the Moore report until July 29, 2016, less than fourteen months before trial. Second, Bayer used what Dr. Moore acknowledges is one of "comparatively few contract laboratories [that] remain equipped" for radioactive DNA labeling. Balcof Decl., Ex. A (Moore Report) at ¶ 56. Biogen searched for another lab that could do it, and initially identified Charles River Laboratories. *See* Balcof Decl., Ex. N (September 29, 2016 e-mail). But Charles River at first stated that it would take months and then ultimately stated that it could not perform such testing at all. *Id.*

II. The Prejudice Cannot Be Cured And Threatens The Trial Date Biogen Has Sought Since This Action Began In 2010

The second and third *Pennypack* factors likewise militate in favor of striking Dr. Moore's report. Biogen expects that Bayer will argue to the Court, as it argued

during the meet-and-confer, that there is "plenty of time" for Biogen to respond to the Moore report before trial. This defies the experience of the last six years. Reopening claim construction threatens new claim construction proceedings, a new claim construction decision, new expert opinions, and new fact and expert discovery to address the new claim construction positions and opinions, which Bayer could easily have avoided by timely honoring its disclosure obligations.

III. Bayer Knowingly And Willfully Disregarded The Scheduling Order

In March 2013, Bayer stated that it was "not withholding or refusing to identify documents or testimony that it currently believes are responsive to Biogen's interrogatories," and "at this time we do not believe there is anything to add and compel." Balcof Decl., Ex. K (March 22, 2013 e-mail). To this day, Bayer has offered no explanation as to how it could possibly have made this statement given that it was sitting on the as-yet undisclosed results of the testing it conducted in 2011-2012.

CONCLUSION

For the reasons set forth above, the Court should strike the Moore report and preclude Bayer from using the underlying "capable of hybridizing" invalidity contention and supporting information at trial or in other proceedings in this action.

Dated: October 11, 2016
Chatham, New Jersey

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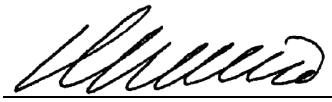
By: 

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